

European Directorate for the Quality of Medicines (EDQM)

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The Council of Europe

46 member states



Ph.Eur. membership

- 36 member states incl. the EU
(*Poland 21.12.2006*)
- 20 observers incl. USA/FDA
(Blood Products)+ WHO

Ph. Eur. Members & Observers



Role of the Ph. Eur.

- Harmonised quality standards for use by health professionals
- Mandatory in European MA dossiers in 36 Member States (Ph.Eur.Convention)
- Recognised as the only official Pharmacopoeia in Europe, to be used for international trade

Groups of experts

- Composed of experts from Member States
- Proposed by the national authorities, appointed by Ph.Eur. Commission
- Chaired by a member of the Ph.Eur. Commission
- 3-year term of office, renewable once

Working methods

- Work programme: decided by the Ph.Eur. Commission
- Proposals from: delegations, groups of experts, EDQM secretariat
- Elaboration of monographs allocated to a group of experts or working party
- Final adoption by Ph.Eur. Commission

The European Pharmacopoeia

- 6th Edition (1.01.2008)
- International harmonisation with JP, Ph.Eur., USP
- Functionality-related characteristics in excipient monographs
- Control of impurities in API's
- Certification scheme
- Electronic communication: Helpdesk